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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/632,149	08/03/2000	R. Andrew Cuthbertson	A-59553-2 DAV JJD	1941

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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	17

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Commissioner of Patents and Trademarks

SEE ATTACHMENT:

DETAILED ACTION

Response to Amendment

The reply filed on April 22, 2002 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Applicants do not further elect a patentably distinct genetic ocular disease in Group I as set forth on page 3 in the Office Action dated 03/11/02 in Paper No. 14. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a) from the date set forth in the previous Restriction requirement in Paper No. 14 (3/11/02). The period for reply expires 4 months from the mailing date of the previous Restriction requirement.

For the purpose of a compact prosecution, Applicants' amendment filed April 22, 2002 in Paper No. 16 has been entered. Amended claims 13-24 are pending in the present application. For Applicants' convenience, following is the election/restriction requirement already set forth in the previous Office Action taken into account of Applicants' amendment filed April 22, 2002 in Paper No. 16.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 13-21, drawn to a method of alleviating the degeneration of ocular cells due to an ocular disease, said method comprising directly contacting an ocular cell *in situ* with an exogenous nucleic acid under conditions permissive for the direct uptake of said exogenous nucleic acid, said exogenous nucleic acid encoding a protein associated with said ocular disease, whereby said exogenous nucleic acid is expressed in said ocular cell, classified in class 514, subclass 44.

II. Claim 22, drawn to a method of alleviating the degeneration of ocular cells due to an ocular disease wherein the disease is lysosomal storage disease utilizing an exogenous nucleic acid encoding a protein associated with said ocular disease, said method, classified in class 514, subclass 44.

III. Claims 23 and 24, drawn to a method of alleviating an ocular wound or alleviating an ocular wound after surgery utilizing an exogenous nucleic acid encoding a protein useful in alleviating the ocular wound, classified in class 514, subclass 44.

Should Group I be elected, further **group restriction** is required because claim 13 links a plurality of disclosed patentably distinct genetic ocular diseases that lack the unity of invention. The following ocular genetic diseases have no common underlying genetic mutations causing the diseases or symptoms or disease progression courses: (a) autosomal retinitis pigmentosa, (b) autosomal dominant retinitis punctata albescens, (c) butterfly-shaped pigment dystrophy of the fovea, (d) adult vitelliform macular

dystrophy, (e) Norrie's disease, (f) blue cone monochromasy, (g) choroideremia, and (h) gyrate atrophy. For examples, autosomal retinitis pigmentosa is caused by many as 50 different mutations in the rhodopsin gene, autosomal dominant retinitis punctata albescens is associated with a mutation in the peripherin/RDS gene, gyrate atropy is involved with more than 60 different mutations in the mitochondrial enzyme ornithine aminotransferase, and Norrie's disease, blue cone monochromasy and choroideremia are caused by different genetic mutations.

The restriction requirement between linked inventions is subject to the non-allowance of the linking claim 13. The restriction requirement between linked inventions is subject to the non-allowance of the linking claim(s), 13.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: The methods in groups I-III are distinct and they are not required one for the other. They require different starting materials (e.g., a patient with a genetic ocular disease in Group I, a patient with an ocular lysosomal storage disease in Group II, and a patient with an ocular wound which is not even a disease let alone a genetic disease in Group III, together with different exogenous nucleic acid molecules encoding for proteins associated with or appropriate for the different ocular diseases or ocular wounds) and different desired therapeutic endpoints.

Because these inventions are distinct for the reasons given above and require separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER